UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION (TOLEDO)

TINA BURRIS	)	
	)	
Plaintiff,	)	Case No.: 3:20-cv-01450-JRK
	)	
v.	)	
	)	JUDGE JAMES R. KNEPP II
ETHICON, INC., et al,	)	
	)	
Defendants.	)	

PLAINTIFF'S TRIAL BRIEF

Dated: June 3, 2022

Respectfully submitted,

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STATEMENT OF THE FACTS

I. The Parties

This trial involves product liability and related claims against Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon")[1] arising from an August 5, 2008 surgery implanting into Plaintiff Tina Burris the Gynecare Prolift Anterior Pelvic Repair System (the "Prolift"). The operation was performed by Dr. Desrene Brown at Bluffton Hospital-Blanchard Valley Health System in Bluffton, Ohio. Dr. Brown was not adequately informed by Ethicon of the Prolift's risks -- including the most severe risks of the Prolift procedure and device. Consequently, Dr. Brown was not in a position to disclose those risks to Ms. Burris.

II. The Prolift

Pelvic organ prolapse occurs when pelvic floor muscles become weak or dysfunctional and cease supporting the organs in the pelvic area, causing connective tissue attachments to stretch or break and organs to become displaced. In 2002, Ethicon began to market Gynemesh PS to treat pelvic organ prolapse. Gynemesh PS used the same polypropylene mesh marketed as Prolene Soft, which had previously been used in hernia repairs. Gynemesh PS was sold in flat rectangular sheets of two different sizes that a surgeon could cut into the appropriate shape and then stitch into place. Ethicon designed Gynemesh in two sizes for vaginal and abdominal approaches; it did not provide tools for insertion. On January 8, 2002, Ethicon received 510(k) clearance from the FDA for the use of Gynemesh PS in the pelvic floor.

Around that same time, beginning in 2000, a group of gynecological surgeons in France began an exploratory program to develop a transvaginal mesh (TVM) procedure to treat pelvic organ prolapse. The French TVM group worked with Ethicon and its Gynecare division, which coordinated the group's logistics. The group ultimately developed an approach that consisted of a

pre-cut mesh implant and the instruments need to perform a vaginal repair. They used the same mesh material as Gynemesh PS, *i.e*. Prolene Soft, and designed a system to insert the mesh in the pelvic area. This would become the Prolift.

The Prolift procedure inserted a much larger volume of mesh into the pelvic space than did Gynemesh PS. The large mesh arms extended into the depths of the pelvis, ostensibly to provide support for the prolapsed organ(s). Here, Ms. Burris underwent an Anterior Prolift repair, which entailed placing four mesh arms into her groin through the obturator internus muscle. As designed by Ethicon, the mesh and arms were introduced and then pulled through the vagina and pelvis, including through anatomical areas that had no defect or weakness whatsoever, by use of large, sharp trocars, and the arms then pulled out through skin incisions in the groin, abdomen, and buttocks.

In April 2003, Ethicon held a "kickoff meeting" for the Prolift exploratory project. Scott Ciarrocca, who became the research and development project leader, was responsible for design control activities and the accumulation of documents for the design history profile. His team performed design verification studies to test mesh thickness, tear strength, and dimensions. On July 19, 2003, Ciarrocca received an email from Professor Michel Cosson, an academic surgeon and member of the French TVM group, that identified problems with the mesh material including erosion (exposure through the vaginal wall or into organs), contraction (formation of scar tissue around the mesh that results in shrinkage, or contraction), and recurrence (the return of prolapse). Cosson wrote that if erosion or recurrence occurred due to the mesh, the team needed "to go back into the concept stage, delay launch and increase resources."

On October 6, 2004, Sean O'Bryan, who developed the regulatory strategy for Prolift at the project's inception, advised Ciarrocca that FDA Guidelines did not require a new 510(k)

premarket notification. He assumed that the differences between Gynemesh PS and Prolift were not significant enough to warrant a new 510(k) clearance. As Ethicon later learned, the Prolift did require clearance but was not cleared until approximately three years after its launch—in fact, the FDA was unaware of the Prolift's release at the time it launched—and Ethicon applied for 510(k) clearance only after directed to do so by the FDA.

In 2004, Ethicon prepared Prolift's "instructions for use" (IFU), which was written for the implanting surgeon and packaged with every Prolift kit. It advised physicians that the "[f]ailure to properly follow instructions may result in improper functioning of the devices and lead to injury," and that training was recommended and available. The IFU stated that the Prolift total, anterior or posterior pelvic floor repair systems were indicated for "tissue reinforcement and long-standing stabilization of fascial structures of the pelvic floor in vaginal wall prolapse." The IFU identified potential adverse reactions, including: "those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction." Other identified adverse reactions included "[p]unctures or lacerations of the vessels, nerves, bladder, urethra, and bowel" that might occur during guide passage and require surgical repair.

Charlotte Owens, M.D., who joined Ethicon as worldwide medical director in 2003 and left in August 2005, testified at her deposition that she understood the IFU document had to be clear, unambiguous, accurate, and supported by data, and she claimed the IFU communicated all contraindications, warnings, precautions, and adverse reactions to physicians. However, she also acknowledged that she approved the IFU even though she knew there might be long-term complications.

On January 11, 2005, Arnaud, the scientific director of Gynecare Europe, sent an email to

Ophelie Berthier, the product director who oversaw the marketing launch of Prolift worldwide, proposing to add the following warning to the IFU:

> Warning: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction, which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggests the risk of such a complication is increased in cases of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.

Berthier advised Ciarrocca it was "quite urgent" to incorporate the changes in the IFU version in the procedure CD-ROM. Ciarrocca forwarded this email to O'Bryan and Owens, asking whether it was "okay to add such a sentence as it is being proposed without FDA approval." On January 13, 2005, O'Bryan responded: "We can change the adverse event to whatever is most appropriate without FDA implications. I will leave it to Charlotte [Owens] and Axel [Arnaud] to decide." O'Bryan noted that the IFU had already been approved through an internal process used to review important labels, and that it most likely had "gone out for translations," meaning it was in the hands of the printer. Ciarrocca replied: We have already printed launch stock. This would be a next revision addition, but they want it in there ASAP.

At his deposition, he acknowledged the proposed warning was not included in the first IFU because Ethicon did not want to reprint it, noting a motivation to get the product to market as soon as possible. The warning, however, also did not appear in the next revision.

On January 14, 2005, Owens issued a clinical expert report to document the "safety and functionality" of the Prolift system to treat pelvic floor repair. She relied on a Gynemesh PS clinical study that was ongoing when she arrived at Gynecare as the foundation from which to draw relevant information for her clinical report. That study was performed by multiple physicians using Gynemesh PS for vaginal and abdominal placements; the Owens' clinical report on Prolift

listed the same potential complications identified in the Gynemesh PS study, such as "[i]nfection, mesh exposure, fistula, hematoma, and contraction." She reported there were no instances of tissue contraction in the Gynemesh clinical evaluation. At the time she authored this clinical expert report, however, Owens admitted she was familiar with a 2004 article published by the French TVM group that identified retraction as a potential complication along with such after effects as dyspareunia and severe pain. Owens did not cite the article in her clinical report or discuss the possibility of retraction.

Owens testified that surgeons were expected to inform their patients of potential risks associated with any pelvic floor repair, including uncomfortable sexual relations. She acknowledged Prolift represented the first time the mesh material was marketed "in that shape, size, with those instruments, [and] with that accompanying procedure," and she also acknowledged she had only performed the Prolift implant in cadavers.

Owens testified that, before the market launch of Prolift, she knew the mesh could erode, migrate, or lead to inflammation and, also, that removal of mesh could be very difficult even though Ethicon did not conduct studies on how to remove it. She also knew the guide process through the pelvis could damage the pudendal nerve, which innervates parts of a woman's pelvis that allow for normal urinary and bowel function.

Arnaud similarly testified at his deposition that, prior to Prolift's launch, he was aware of such potential problems as erosion and retraction of mesh with potential risks of pain, dyspareunia, and prolapse recurrence. He was also conscious of the need to improve the mesh material to reduce stiffness in the area of the implant where scar tissue formed and shrinkage occurred. Arnaud admitted that, at the time, he did not understand the mechanism of erosion or know how to reduce mesh shrinkage. In his view, it was the surgeon's responsibility to develop solutions if a patient

experienced complications.

Ethicon first placed the Prolift on the market in March 2005. At the time of launch, Ethicon had not conducted a clinical study on live people. Prior to that, Defendants conducted two clinical studies:

- The Gynemesh PS Study was a study of the mesh material itself inserted in various ways (but not through the Prolift procedure); and
- The TVM Studies, performed in a French arm and a US arm, in which the mesh material was shaped similar to the ultimate shape of the Prolift, and inserted through various instruments (but not with the Prolift instruments, i.e., trocars).

The data from both studies showed significant complications at alarming frequency.

After the Prolift was released, Ethicon began to accumulate data and information provided by surgeons regarding Prolift mesh and procedure complications – including particularly intractable, untreatable, pain and dyspareunia (painful sexual intercourse).

On March 22, 2005, Cosson and other members of the French TVM group published an article discussing the results of a study of 277 patients eight weeks after Prolift surgery. They found that thirty-four patients experienced mesh exposure and, after a month of treatment, twenty-five required surgery. Based on this data, the authors advised that "caution be exercised when carrying out this new surgical procedure" and suggested "experimental studies and clinical trials . . . in order to reduce the level of exposure to less than 5% of cases."

On June 27, 2006, the French TVM group published the results of its study of 106 patients to determine the recurrence of prolapse twelve months post-procedure. The results did not meet the pre-defined criteria of success, which defined a prolapse recurrent rate of less than twenty percent. Nonetheless, they concluded that the study demonstrated "reasonable success rates" and

a recurrence rate that compared favorably "with reoperation rates of around 30% using traditional vaginal approaches in other studies."

On February 23, 2007, Cosson wrote that it might be possible to improve polypropylene mesh in terms of shrinkage and that a new material might be needed. In an email dated October 29, 2008, Jonathan Meek, worldwide marketing director for Ethicon, described polypropylene as "the best of a bad lot" with respect to integration and retraction, saying there was "a need to develop grafts that mimic the human tissue mechanical properties."

Meanwhile, as early as January 2005, Gene Kammerer, an engineer at Ethicon, suggested the possibility of using Ultrapro mesh for pelvic floor repair in place of Gynemesh. In an email dated April 13, 2005, he wrote that surgeons and customers wanted a better mesh to reduce contraction and scar tissue and that Ultrapro would make the procedure better for patients and give Ethicon a significant advantage over the competition. Kammerer said Ultrapro had a lower inflammatory response, left behind less material than Prolene Soft, and had a larger pore size than Gynemesh PS to better allow the ingrowth of tissue.

This led Ethicon to develop and market the Prolift +M: a product Defendants billed as a more “natural,” and thus safer alternative. The Prolift +M was the same Prolift procedure and instruments (trocars), but the mesh used was partially absorbable (+M signifies the Monocryl component – which was absorbable). The goal of the Prolift +M was to leave less mesh material, with larger pores and lighter weight, in a woman’s body, and consequently reduce the inflammatory reaction, resulting scarring, and other complications.

Ultimately, Ethicon ceased marketing and selling the Prolift and Prolift +M. Ethicon also changed the warnings (indications) for the Gynemesh PS (Prolift’s predecessor) to indicate for abdominal placement only, and no longer vaginal placement, as of September 1, 2012.

III. Plaintiff's Damages

In this case, Plaintiff Tina Burris has endured persistent complications, pain, disruption of her life, and significant medical and surgical treatment, including but not limited to the following:

- Pudendal neuralgia (and possible obturator neuralgia);
- Permanent and life-altering pelvic pain, groin pain, vaginal pain, and leg pain;
- dyspareunia and chronic sexual disfunction.
- chronic numbness in legs;
- heavy scarring of the mesh known as bridging fibrosis and scar plates, leading to painful contraction, tightening, and bunching of the mesh;
- worsened urinary complaints;
- inability to sit, stand, or walk for extended periods of time due to pain;
- multiple revision surgeries and procedures, and extensive medical treatment for complications;
- urethral injury;
- inability to enjoy pre-implant activities; and,
- psychological distress, including anxiety and depression.

Ethicon knew all of the risks associated with the Prolift before the devices were marketed. These significant risks were not disclosed by Ethicon to physicians, including Plaintiff's implanting physician, Dr. Desrene Brown. To the extent Ethicon did not know of these risks before Ms. Burris's implant, Ethicon learned of them after her implantation, and failed to disclose them to physicians, including Dr. Brown. Ethicon thus fell below the standard of care required of a reasonably prudent medical device manufacturer by its failure to warn of

these risks.

IV. Ethicon's Failure to Warn Dr. Brown

Plaintiff Tina Burris received the Prolift device in August 2008 at the age of 43. Plaintiff's implanting physician, Dr. Desrene Brown, discussed with Plaintiff the general surgical risks associated with the Prolift as she knew them. She testified at her deposition that she read and relied upon the Prolift's Instructions for Use when learning about the risks of the Prolift. In fact, she was trained on the implant of the Prolift at an Ethicon course that certified her to perform the procedure.

In the normal course of her practice, she provided patients with the manufacturer's brochure at their consent discussion, and testified that Ms. Burris would have received one before her implant procedure.

Sometime after Dr. Brown performed Ms. Burris's Prolift surgery, she suspended any further use of the Prolift device. She testified that the frequency of mesh erosions had become a topic of conversation among gynecologists and surgeons, and then the American College of Obstetrics and Gynecology (ACOG) recommended that implanting physicians emphasize at the consent appointment not just the frequency of complications, but also the fact that chronic complications could occur even after mesh removal. She learned of complications related to "long-term chronic pelvic pain and pain with intercourse" through her review of the medical literature. As she stated, there "are always potential complications … in pelvic surgery [but] the frequency and the association with the mesh is something that [she] learned about afterwards." Dr. Brown eventually ceased performing mesh implantation of anterior repairs altogether.

Dr. Brown testified that she wanted as much information about a product that would be implanted into a patient as she could receive. Further, if there was important knowledge of the manufacturer about a product, like the Prolift, she agreed that it would be important for it to be

placed in the instructions. Had she received important information from Ethicon about their product, she would have conveyed that information to Ms. Burris as part of the informed consent discussion. As it were, Dr. Brown did not receive or convey information about, for example, the risk of permanent and chronic pain.

Dr. Brown agreed that she should be able to count on the truthfulness of a manufacturer's warnings, and if a manufacturer knew about a risk, she would have wanted to know about that risk. However, despite having had Ethicon sales representatives attend and observe "most" of her Prolift surgeries, she did not recall them ever discussing with her anything outside of what she learned at her implant training.

Finally, Dr. Brown testified that she agreed that manufacturers must perform adequate studies to determine whether a device is safe and adequate. She would not have recommended a product to Ms. Burris otherwise.

DISCUSSION OF CONTROLLING LAW

In this action, Plaintiff Tina Burris asserts a failure-to-warn claim under the Ohio Products Liability Act ("OPLA"). Additionally, Plaintiff seeks to recover punitive damages pursuant to the New Jersey Punitive Damages Act ("PDA").

Failure to Warn. To prevail on a failure to warn claim under Ohio law, a plaintiff must prove three elements: (1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury proximately caused by the breach. *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003). Ohio's failure to warn statute, entitled "When product is defective due to inadequate warning or instruction" provides:

> (A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:
>
> (1) It is defective due to inadequate warning or instruction at the time of

marketing if, when it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

(C) An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Rev. Code Ann. § 2307.76.

Ohio law provides that "[a] plaintiff not only must convince the fact finder that the warning

provided is unreasonable, hence inadequate, but he also must establish the existence of proximate cause between the [product] and the fact of the plaintiff's injury." *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010) (quoting *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 450-51 (6th Cir. 2000)) (further citation and brackets omitted). "In analyzing the proximate cause issue as it relates to failure-to-warn cases, the Ohio Supreme Court divided proximate causation into two sub-issues: (1) whether the lack of adequate warnings contributed to the plaintiff's use of the product, and (2) whether use of the product constituted a proximate cause of the plaintiff's injury." *Fulgenzi v. PLIVA, Inc.*, 140 F. Supp. 3d 637, 649 (N.D. Ohio 2015); *Hisrich*, 226 F.3d at 451 (quoting *Seley v. G.D. Searle Co.*, 67 Ohio St. 2d 192, 423 N.E.2d 831, 838 (Ohio 1981)) (internal quotations and brackets omitted).

Notably, under Ohio law, "where no warning is given, or where an inadequate warning is given, a rebuttable presumption arises, beneficial to the plaintiff, that the failure to adequately warn was a proximate cause of the plaintiff's [use] of the [product.] This presumption, absent the production of rebutting evidence by the defendant, is sufficient to satisfy the first branch of the plaintiff's proximate cause burden." *Seley*, 67 Ohio St.2d at 200; *Hisrich v. Volvo Cars of N. Am., Inc*., 226 F.3d 445, 451 (6th Cir. 2000) ("Under Ohio law, the presumption exists at the outset and accrues to the benefit of the plaintiff. Thus, it is the defendants who must establish that proximate cause is deficient by rebutting the presumption that [the driver] read and heeded the instructions.") (internal citations omitted).

The Ohio Supreme Court articulated a clear standard for determining the adequacy of warnings:

> The fact finder may find a warning to be unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is conveyed. The adequacy of such warnings is measured not only by what is stated, but also by the manner in which it is stated. A reasonable warning not only conveys

> a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk. A warning may be found to be unreasonable in that it was unduly delayed, reluctant in tone or lacking in a sense of urgency. A jury may find that a warning is inadequate and unreasonable even where the existence of a "risk," i.e., a causal relationship between use of the product and resulting injury, has not been definitely established. Thus, where scientific or medical evidence exists tending to show that a certain danger is associated with use of the drug, the manufacturer may not ignore or discount that information in drafting its warning solely because it finds it to be unconvincing.

Seley v. G. D. Searle & Co., 67 Ohio St. 2d 192, 198, 423 N.E.2d 831, 837 (1981); *Bowles v. Novartis Pharm. Corp*., No. 3:12-cv-145, 2013 U.S. Dist. LEXIS 134350, at *26-27 (S.D. Ohio Sep. 19, 2013) (holding that "the question of whether the manufacturer exercised 'reasonable care' encompasses both the *content* of that warning and the *method* by which the manufacturer disseminates that warning").

Ohio also holds manufacturers like Ethicon to a standard of care/knowledge related to failure to warn claims:

> **MANUFACTURER'S STANDARD OF CARE/KNOWLEDGE:** One who manufactures a product for sale is held to the skill of an expert in that business and to an expert's knowledge of the arts, materials, and processes involved in the development, production, and marketing of the product. The manufacturer has the duty to remain reasonably current with scientific knowledge, development, research, and discoveries concerning the product. The manufacturer must communicate its superior knowledge to those who, because of their own limited knowledge and information, would otherwise be unable to protect themselves.
>
> However, a manufacturer need not instruct or warn (regarding the use of its product) unless and until the state of medical, scientific, and technical research and knowledge has reached a level of development that would make a reasonably prudent manufacturer aware of the unreasonable risks of harm created by the product and aware of the necessity to instruct or warn (ordinary users of the product) against such risks of harm.

OJI CV 451.07 (Statutory failure to warn); *Hutchens v. Abbott Labs., Inc*., No. 1:14CV176, 2017 U.S. Dist. LEXIS 193494, at *29 (N.D. Ohio Nov. 22, 2017).

Punitive Damages. It is Plaintiff's position that New Jersey's punitive damages statute applies to Plaintiff's claims. Plaintiff must first address Defendants' contention that Missouri choice-of-law principles should apply, as this argument misrepresents the procedural facts of this case. Plaintiff did not file her case in Missouri and then transfer into the MDL—she filed her short form complaint directly into the MDL in West Virginia. Plaintiff concedes that her short-form complaint erroneously lists the "State of Missouri – Eastern Division" as the District Court and Division in which venue would be proper, but it is obvious from the facts of this case that the Northern District of Ohio is the proper venue. Plaintiff resides in the Northern District of Ohio, and her injuries were sustained and treated in the Northern District of Ohio, and the MDL Court, the parties, and this Court all recognized such when this case was properly transferred to the Northern District of Ohio from the MDL. Missouri has no connection to the substantive facts of this case whatsoever.

While Ms. Burris was listed as one plaintiff among many in a products liability petition brought against the Defendants in Missouri state court, this was ***not*** because Missouri is the most appropriate venue for her individual claims. At no point was Ms. Burris (or, indeed, most of the plaintiffs named in this initial petition) a resident of Missouri, nor was she injured in Missouri or treated for any of her injuries in Missouri. Instead, the non-resident plaintiffs filed in Missouri state court to avail themselves of Missouri's permissive joinder rule (Mo. Sup. Ct. R. 52.05(a)), which allows the permissive joinder of multiple plaintiffs asserting rights that arise out of the same transaction, occurrence, or series of transactions or occurrences, and Missouri's venue statute (Mo. Rev. Stat. § 508.010(5)(1)), which states that when a non-resident plaintiff injured outside of Missouri files suit against a corporate defendant, venue lies in any county where a defendant corporation's registered agent is located. The Missouri state court petition obliquely

referenced by the Defendants did not establish that Missouri was the best or most appropriate forum for each individual plaintiff, but rather it was a mechanism by which to consolidate suit against Johnson & Johnson—whose registered agent was located in St. Louis—on behalf of multiple plaintiffs—most or all of whom were not Missouri residents—whose injuries arose our of the same series of transactions and occurrences, namely the failure of the Defendants' defective mesh products. Nothing in this procedural history suggests that Missouri was the "court of proper venue" for Ms. Burris's individual claims, as contemplated by the Sixth Circuit in *Wahl v. General Elec. Co.*, 786 F.3d 491, 497 (6th Cir. 2015).

Regardless, Defendants' contention that Missouri law should apply fails because Missouri was ***not***, in fact, where Plaintiff initially filed the case pending before this Court. The Missouri action has no procedural connection to the MDL or the matter before this Court. A thorough review of the dockets of the 22nd Circuit Court in St. Louis and the Eastern District for Missouri demonstrated that this Missouri action was transferred to federal court almost immediately after the service of the petition on the Defendants and was subsequently remanded back to Missouri state court, where it appears to still be pending. Plaintiff Tina Burris is no longer represented by the attorneys who filed the Missouri action, and with the help of new counsel, Plaintiff direct-filed a short form complaint into the West Virginia MDL on August 1, 2014. That is the initial filing for the purposes of this case. Where a case is direct-filed into an MDL, then remanded to the court of proper venue, the choice-of-law procedures of the proper venue must be applied, so as to avoid an "accident of bureaucratic convenience." *Wahl*, 786 F.3d at 496. The naming of Plaintiff in a lawsuit prior to her direct-filing a complaint in the MDL—a lawsuit in which she is no longer participating, filed by attorneys who no longer represent her—is irrelevant to any choice-of-law issues before this Court. If Defendants honestly believed that Missouri was the

most convenient forum for this action, they should have raised this argument at the time the MDL Court sought to transfer the case. Instead, they have remained silent until now and seek to apply Missouri choice-of-law principles only because they believe it will provide them with a more favorable punitive damages analysis. Missouri has no relation to this case, and Defendants' argument that its law should be applied is not made in good faith. It is clear from the facts before the Court that the Northern District of Ohio is the court of proper venue, and Ohio choice-of-law principles must be applied.

Because there is a conflict between Ohio law and New Jersey law on punitive damages, the Court must analyze the competing "governmental interests" of both states to determine which state has the most significant relationship to the issue. The Southern District of Ohio spoke to this issue in a factually analogous case, *Williams v. Novartis Pharm. Corp.*, 15 F. Supp. 3d 761, 768-69 (S.D. Ohio 2014), stating: When a plaintiff seeks punitive damages against a manufacturer in a products liability case based on a "failure to warn" theory, the focus, for purposes of a choice-of-law analysis, needs to be on the place where the defendant's alleged corporate misconduct occurred. *Id.* (citing Restatement (Second) Conflict of Laws § 145 cmt. e ("when the place of the injury . . . is fortuitous . . . the place where the defendant's conduct occurred will usually be given particular weight . . ."). In the *Williams* case, the vast majority of the alleged corporate misconduct took place at the manufacturer's headquarters in New Jersey, and therefore the court deemed New Jersey to be "the place where the conduct causing the injury occurred." *See* 15 F. Supp. 3d 761 at 769.[1] The Southern District of Ohio went on to explain:

[1] The majority of courts that have addressed this issue in other cases involving drugs or medical devices have concluded that New Jersey has the most significant relationship to the punitive damage claims. *See, e.g.*, *Krause v. Novartis Pharms. Corp.*, 926 F. Supp. 2d 1306 (N.D. Fla. 2013) (collecting cases); *Mathews v. Novartis Pharms. Co.*, 953 F. Supp. 2d 811, 815-16 (S.D. Ohio 2013 (collecting cases); *Guenther v. Novartis Pharms. Corp.*, No. 6:08-cv-456, 2013 U.S. Dist. LEXIS 43518, 2013 WL 1225391, at *2 (M.D. Fla. March 27, 2013) (collecting cases).

> "In determining which state has the most significant relationship to the punitive damages issue, the Court must also consider the policy considerations set forth in Restatement (Second) of Conflict of Laws § 6.2 These factors also support the application of New Jersey law. *See Zimmerman v. Novartis Pharms. Corp.*, 889 F. Supp. 2d 757, 763-64 (D. Md. 2012). Ohio's interest in making sure that its residents are adequately compensated for injuries occurring within its borders is satisfied by the application of Ohio law to the issue of liability.
>
> Admittedly, Ohio may also have some interest in punishing and deterring manufacturers who market dangerous drugs to its citizens. However, when the corporate conduct at issue occurs outside Ohio, that interest is generally outweighed by the interest of the state where the alleged misconduct occurred. As the court held in *Brown v. Novartis Pharmaceuticals Corp.*, No. 7:08-cv-130, 2012 U.S. Dist. LEXIS 104985, 2012 WL 3066588, at * 8 (E.D.N.C. July 27, 2012), [the manufacturer] has a justified expectation that New Jersey law will govern the question of whether punitive damages are warranted for its conduct within that state, and "application of New Jersey law to the issue of punitive damages will promote certainty, predictability, and uniformity of result."

See id. Accordingly, although the plaintiffs in that case were domiciled in Ohio and their injuries occurred in Ohio, the *Williams* court determined that greater weight should be given to "the place where the conduct causing the injury occurred" because the alleged corporate misconduct giving rise to the claims for punitive damages occurred in New Jersey, where the manufacturer maintained its principal place of business, it was there that the manufacturer allegedly failed to conduct adequate clinical trials, and made decisions about the warnings that would be placed on the drug labels. *See id.*

The *Williams* case is nearly factually identical to the present case for the purpose of the punitive damages choice-of-law issue. The conduct giving rise to Plaintiff's punitive damages claims took place at Defendants' principal place of business in New Jersey, including its failure to conduct adequate clinical trials and its decision-making with respect to warnings before and after Plaintiff's implantation. Therefore, New Jersey's punitive damages statute should apply.

LIST OF PROPOSED WITNESSES

Plaintiff and Family

Tina Burris
Ms. Burris is the plaintiff in this case and will testify regarding her injuries and the facts supporting her allegations against Defendants.

Ricky Dennis Burris
Mr. Burris is Plaintiff's spouse and will testify about his knowledge of Plaintiff's medical, occupational, family, and lifestyle history and medical conditions. He is also expected to testify about his knowledge regarding Plaintiff's alleged injuries and/or damages.

Christine Horning
Ms. Horning is Plaintiff's sister and will testify about her knowledge of Plaintiff's medical, occupational, family, and lifestyle history and conditions. She is also expected to testify about her knowledge regarding Plaintiff's alleged injuries and/or damages.

Plaintiff's Expert Witnesses

Niall T.M. Galloway, M.D.
Dr. Galloway is an Associate Professor of Surgery (Urology) and will testify as a case-specific and general expert witness at trial. He will testify on matters related to Plaintiff's claim of failure to warn. His testimony will be consistent with the opinions set forth in his Rule 26 expert report.

Jimmy Mays, Ph.D.
Dr. Mays is a professor of biomedical engineering with a specialization in polymer materials and a general expert witness in this case. He will testify on matters related to Plaintiff's claim of failure to warn. His testimony will be consistent with the opinions set forth in his Rule 26 expert report.

Jerry Blaivas, M.D., FACS
Dr. Blaivas is a board certified urologist who specializes in the surgical treatment of stress urinary incontinence and pelvic organ prolapse. He will testify on matters related to Plaintiff's claim of failure to warn. His testimony will be consistent with the opinions set forth in his general expert report.

Robert Tremp, Jr., MA, CRC, CLCP, LAC
Mr. Tremp is a certified life care planner. He will testify as a case-specific expert on the variety of physical limitations suffered by Plaintiff and the future care and financial resources that may be needed as a consequence. His testimony will be consistent with the opinions set forth in his

Life Care Plan and Cost Analysis.

Plaintiff's Medical Providers

Desrene Brown, M.D.
Dr. Brown is a board-certified obstetrician, gynecologist, and surgeon who implanted the Prolift device in Plaintiff in 2008. Dr. Brown is expected to testify as to the nature of Plaintiff's medical symptoms, and the diagnosis and treatment rendered to Plaintiff.

Mark Walters, M.D.
Dr. Walters specializes in Urogynecology and Obstetrics & Gynecology. He performed mesh-removal and anatomical repair surgery on Plaintiff in 2011 and 2021. Dr. Walters is expected to testify as to the nature of Plaintiff's medical symptoms, and the diagnosis and treatment rendered to Plaintiff.

Howard Goldman, M.D.
Dr. Goldman specializes in Female Urology/Pelvic Medicine & Reconstructive Surgery and performed mesh-removal and anatomical repair surgery on Plaintiff in 2011 and 2021. Dr. Goldman is expected to testify as to the nature of Plaintiff's medical symptoms, and the diagnosis and treatment rendered to Plaintiff.

Maurice Chung, M.D.
Dr. Chung is a Urogynecology & Reconstructive Pelvic Surgery Specialist who treated Plaintiff for pelvic pain and other symptoms, including injections to treat pudendal neuralgia, in 2014 and 2015. Dr. Chung is expected to testify as to the nature of Plaintiff's medical symptoms, and the diagnosis and treatment rendered to Plaintiff.

Mark Conway, M.D.
Dr. Conway is a board certified OB/GYN who treated Plaintiff for ongoing pelvic pain in 2020. Dr. Conway is expected to testify as to the nature of Plaintiff's medical symptoms, and the diagnosis and treatment rendered to Plaintiff.

Defendants' Expert Witnesses, Employees and Former Employees

Corporate Representative(s) for Ethicon, Inc. and/or Johnson & Johnson with the most knowledge of the following topics: (1) the history and development of the Prolift device, including the clinical testing allegedly completed for the device; (2) marketing and sales of the Prolift device, from the time of they were first marketed to present date; (3) instruction and training of physicians on proper use of the devices; (4) postmarketing complaints related to Prolift device and Ethicon's response to those complaints; (5) Ethicon's net worth; and (6) Ethicon's affirmative defenses, discovery responses, and denials of Plaintiff's claims.

Angelini, Laura
Ms. Angelini was formerly the vice president, global strategic marketing for Ethicon. She will provide testimony and opinions related to her knowledge, experience, duties, and responsibilities while at Ethicon.

Arnaud, Dr. Axel
Dr. Arnaud was formerly the European scientific director for Ethicon and involved in the development and market release of the Prolift device. He will provide testimony and opinions related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Ciarrocca, Scott
Mr. Ciarrocca was formerly a staff engineer in the R&D department of Gynecare and the research and development project leader for the Prolift. He will provide testimony and opinions related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Hart, James C.
James Hart was formerly the vice president of medical operations at Ethicon from May 2005 to January 2007. At the time of his deposition, he was chief medical officer, and vice president medical affairs of the global surgery group and was considered the highest ranking medical officer at Ethicon. He will provide testimony and opinions related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Hinoul, Dr. Piet
Dr. Hinoul is a urogynecologist and formerly the worldwide medical director at Ethicon. He was responsible for overseeing the safety and effectiveness of Ethicon's mesh products, including for the Prolift device. He will provide testimony and opinions related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Kammerer, Gene
Mr. Kammerer was an engineering fellow at Ethicon. He will provide testimony and opinions related to his knowledge, experience, duties, and responsibilities while at Ethicon.

O'Bryan, Sean
Mr. O'Bryan was formerly a senior product manager in the regulatory affairs department of Ethicon. He will provide testimony related to his knowledge, experience, duties, and responsibilities related to the Prolift and its IFU.

Owens, Charlotte
Ms. Owens was formerly a worldwide medical director at Gynecare. She will provide testimony related to her knowledge, experience, duties, and responsibilities while at Ethicon.

Parisi, Paul
Mr. Parisi was formerly the director of professional education at Ethicon and was responsible for coordinating professional education for Ethicon and providing training to surgeons on the Prolift device. He will provide testimony related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Robinson, Dr. David
David Robinson was formerly the medical director worldwide of Ethicon Women's Health and Urology (aka Gynecare) from Nov 2005 to December 2010. He will provide testimony and opinions related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Selman, Renee
Ms. Selman was formerly the worldwide president of Ethicon Women's Health & Urology. She will provide testimony related to her knowledge, experience, duties, and responsibilities while at Ethicon.

St. Hilaire, Price
Mr. St. Hilaire was formerly a divisional sales manager and marketing director at Ethicon. He will provide testimony related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Weisberg, Martin
Dr. Weisberg was formerly the medical director for Ethicon and involved in the development and market release of the Prolift and Secur devices. He will provide testimony and opinions related to his knowledge, experience, duties, and responsibilities while at Ethicon.

Plaintiff further cross-designate any individuals identified in Defendants' witness list.

INDEX OF PROPOSED EXHIBITS

In accordance with the Court's Trial Order [ECF No. 182], which requires an index of all proposed exhibits containing a brief description of each exhibit, Plaintiff submits her index of proposed exhibits attached as **Exhibit A**.

EVIDENTIARY ISSUES LIKELY TO ARISE AT TRIAL

Many of the evidentiary issues contested by the parties have been briefed in connection with the parties' deposition objections. To avoid unnecessary reproduction of those arguments and

legal authorities, Plaintiff adopts and incorporates herein the arguments and authorities set forth in Plaintiff's Brief Regarding Deposition Designations [ECF No. 193].

Plaintiff addresses anew the issue of whether OPLA statute § 2307.76(A)(2) applies to Plaintiff's failure to warn claim.

I. Section 2307.76(A)(2), which governs Ethicon's postmarket duty to warn, applies in this case.

As part of her failure to warn claim, Plaintiff asserts the Prolift device was defective due to inadequate warning or instruction at the time of marketing, under § 2307.76(A)(1), and was also defective due to inadequate post-marketing warning or instruction, under § 2307.76(A)(2). Defendants accept Plaintiff's claim as to § 2307.76(A)(1) but deny that (A)(2) applies.

Section (A)(2) applies because Ohio law imposes on manufacturers not just the "duty to warn of duty to warn of dangers known to the manufacturer at the time of sale of the product," but also "a duty to warn of dangers that were not obvious at the time of sale but became known to the manufacturer after the product was sold to a consumer." *Linert v. Foutz*, 2016-Ohio-8445, ¶ 26, 149 Ohio St. 3d 469, 475-76, 75 N.E.3d 1218, 1225.

The Ohio Supreme Court explained that the two duties to warn are conceptually distinct. *Linert*, 2016-Ohio-8445, ¶ 29 ("[W]e clarify that a claim for failing to warn after the product is sold is separate from a claim that a warning should have been given at the point of sale."). "The postmarket duty to warn recognizes that even when a product is not defective at the time of sale, a manufacturer may be subject to liability if it subsequently learns of dangers attendant to the use of the product or methods to avoid serious risks and fails reasonably to communicate that information to product users." *Linert*, 2016-Ohio-8445, ¶ 31 (internal quotation and citation omitted). Therefore, Ohio courts should "apply the traditional failure to warn claim when a manufacturer … had knowledge of a defect at the time of sale and apply the postsale failure to warn claim when a

manufacturer … learns of the defect after the time of sale." *See id*. (internal quotations and citation omitted).

The question for the jury to determine is *when* Ethicon manifested knowledge of the particular risks posed by the Prolift that are relevant to Plaintiff injuries. If the evidence proffered by Plaintiff demonstrates Ethicon's knowledge of, for example, life-altering pain, pudendal and obturator neuralgia, or severe dyspareunia at or before the time of the Prolift's sale, then subsection (A)(1) will apply. *See* Ohio Rev. Code Ann. § 2307.76(A)(1)(a). If the evidence proffered by Plaintiff demonstrates that Ethicon manifested knowledge of the risks at issue *after* the sale of the Prolift implanted in Ms. Burris, then subsection (A)(2) will apply. *See* Ohio Rev. Code Ann. § 2307.76(A)(2)(a).[2]

Furthermore, under both (A)(1) and (A)(2), Plaintiff must show that a "manufacturer exercising reasonable care," would have provided a warning "in light of the likelihood" and "in light of the likely seriousness," of the alleged harm. Ethicon was clearly aware of the likelihood and seriousness of *some* risks before the point of sale: for example, the jury will hear testimony by Ethicon's corporate witnesses about an email by Dr. Axel Arnaud in which he recommended inserting the following warning into the Prolift IFU:

Warning: Early clinical experience has shown that the use of mesh through a

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[2] Exactly when a manufacturer possesses knowledge is set forth in the parties' Joint Proposed Jury Instruction No. 23 (Notice or Knowledge):

> If it appears from the evidence in the case that a person or corporation had information that would lead a reasonably prudent person or corporation to make inquiry through which that person or corporation would surely learn the facts, then this person or corporation may be found to have had actual knowledge of those facts, the same as if the person or corporation had made such inquiry and had actually learned such facts. The law charges a person or corporation with notice and knowledge of whatever that person or corporation would have learned, on making such inquiry as it would have been reasonable to expect the person or corporation to make under the circumstances.
>
> Knowledge or notice may also be established by circumstantial evidence. If it appears that a certain condition has existed for a substantial period of time, and that the person or corporation had regular opportunities to observe the condition, then you may draw the inference that the person or corporation had knowledge of the condition.

FED-JI § 104:24 (modified).

> vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction, which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggests the risk of such a complication is increased in cases of associated hyster-ectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.

Clearly Ethicon possessed knowledge of the risk of anatomical distortion of the vaginal cavity and its interference with the sexual intercourse of sexually active women before it sold the device that reached Ms. Burris. Other risks, however, were likely unknown until after Ethicon sold the Prolift used with Ms. Burris: For example, the risk that complete removal of the Prolift mesh might involve multiple surgeries and still not fully correct complications like chronic pain, or the risk that some complications could persist as a permanent condition even after surgical intervention. Ethicon did not know of these risks at the time it released the Prolift into the market (and likely did not know of them at the time it sold Ms. Burris's device) because Ethicon never conducted a study with the Prolift device in live patients, much less a long-term clinical study of patients implanted with the device, before it released it to the public in 2005 or before Ms. Burris received her Prolift in August of 2008. In addition, Ethicon failed to conduct studies altogether on how to remove the Prolift mesh, yet expected surgeons would and should know how to remove the mesh.

In other words, it is possible—even likely—that the jury will find Ethicon failed to warn Dr. Brown of certain complications at the time of sale *and* failed to warn her of other relevant complications *after* the time of sale.

II. Relevant MDL *Daubert* Rulings

At the April 19, 2022 pretrial conference, the Court requested citation or documentation related to the specific *Daubert* rulings referenced in the parties' Joint Stipulation as to Certain

Daubert Rulings from the MDL [ECF No. 117]. Plaintiff attaches as **Exhibit B** those MDL *Daubert* rulings relevant to Plaintiff's experts, Dr. Jerry Blaivas and Dr. Jimmy Mays.

III. Relevant MDL Ruling on the Exclusion of 510(k) Evidence

At the April 19, 2022 pretrial conference, the Court similarly requested citation or documentation to the specific rulings by the MDL court regarding its exclusion of FDA 510(k) evidence, which the parties referenced in their Joint Stipulation Regarding FDA Evidence [ECF No. 134]. The MDL court routinely refers back to its opinion in *Cisson* regarding FDA 510(k) Clearance. *See e.g., Bellew v. Ethicon, Inc*., No. 2:13-cv-22473, 2014 U.S. Dist. LEXIS 165709, at *28-29 (S.D. W. Va. Nov. 25, 2014) ("The plaintiff seeks to exclude any evidence related to the FDA's 510(k) clearance of the Prolift. In every previous case in these MDLs, this court has excluded evidence regarding the 510(k) clearance process of the product at issue. I see no reason to depart from this position, which I succinctly described in *In re C. R. Bard, Inc*."). In *Cisson*, the MDL court held the following:

> After reviewing the motions, responses, and exhibits thereto, I FIND that evidence as to the FDA's 510(k) process and lack of enforcement action should be excluded under Federal Rule of Evidence 403 because of the danger of misleading the jury, confusing the issues, and unfair prejudice. Given the parties' filings throughout this case, it is abundantly clear that there would be a substantial mini-trial on the 510(k) process and enforcement should it be allowed. In short, this evidence poses a substantial risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims, and if such evidence comes in via expert testimony, the expert would effectively be offering a legal conclusion.

In re C. R. Bard, Inc., No. MDL No. 2187, 2013 U.S. Dist. LEXIS 90210, at *5-6 (S.D. W. Va. June 27, 2013).

PROPOSED VOIR DIRE QUESTIONS

1. This case involves transvaginal mesh implants that treat pelvic organ prolapse and stress urinary incontinence. The mesh, also known as a pelvic mesh, is placed surgically via the vagina and intended to provide permanent support to weakened tissues. Is there anything

about this subject matter that causes you to believe that you could not consider the evidence fairly, impartially, and according to my instructions on the law?

2. Have you, a family member, or close friend ever had a mesh product implanted? That includes transvaginal mesh and hernia mesh.
    a. Please identify the person(s), what the mesh was being used to treat, and the outcome of that experience.
3. Have you, a family member, or close friend ever had some other medical device implanted?
    a. Please identify the person(s), what kind of device it was, and tell us about the outcome.
4. By a show of hands, who has heard about lawsuits involving any medical device, including TVM? That includes word of mouth, something you read, or something you saw on TV.
    a. Is there anything about that knowledge that would make it difficult for you to serve as a fair and impartial juror in a case involving a medical device?
5. Is there anything else that you think might affect your ability to be fair and impartial to *both* sides of a product defect case against a medical device manufacturer?
    a. Please tell us about that.
6. The defendant in this case is Ethicon, which is a subsidiary of Johnson & Johnson. Who here is familiar with Ethicon?
    a. In what capacity have you heard of them?
7. Who here currently owns stock in Johnson & Johnson?
    a. Is that stock part of your retirement savings? How long have you owned that stock?
8. Who here is a current or former business owner?
    a. What type of business?
9. For all the jurors in the box, please stand up and tell us about yourself.
    a. Current occupation (former, if retired or currently unemployed).
    b. Memberships in any groups or organizations.
    c. Hobbies and leisure-time activities.
    d. Primary source of news, including any specific channels or websites
10. Have you or anyone close to you ever worked for:
    a. Johnson & Johnson, or a subsidiary of Johnson & Johnson
    b. Any medical device company
    c. A state or federal regulatory agency (e.g. FDA)

d. The insurance industry

e. A health care facility (e.g., hospital, physician's office, medical clinic)

11. Who here has experience in either engineering, or product design/testing?

    a. Please tell us about that.

12. This case involves a medical device regulated by the Food & Drug Administration ("FDA"). Do you have any personal experience with the FDA, specifically with regard to its rules, procedures, or governance of medical devices?

    a. What is that experience?

13. Who here has strong views, favorable or unfavorable, about oversight by government agencies, such as the FDA's oversight of medical products?

    a. What are those views?

14. Some people feel that all medical devices have risks and when a patient agrees to a medical implant, that patient is agreeing to all risks that come with that device. Therefore, it is unfair to blame the manufacturer if that patient does not get the expected results. Who goes along with that idea, even a little bit?

15. Some people believe all medical devices have risks and when a patient agrees to have a medical implant, that patient is agreeing to all risks that come with that device. Who goes along with that idea, even a little bit?

16. Who here feels that, in order to win a lawsuit, the plaintiff should be required to prove that the defendant intended to cause harm? That is, a corporation is only responsible for intentional misconduct?

17. Ohio law does not require a plaintiff to prove fault by absolute certainty; it merely requires the plaintiff to show that fault is "more probable than not." Would anyone here require Plaintiff to meet a higher burden of proof than "more probable than not"?

18. Excluding divorce and custodial issues, who has been sued yourself, either individually or as a business owner?

    a. Please describe the circumstances.

19. Who here has considered filing a lawsuit – or perhaps could have filed a lawsuit – but then decided against it?

    a. Tell us the circumstances of the potential lawsuit and why you decided not to sue.

20. Who here has negative feelings about personal injury lawyers?

    a. What has lead you to feel that way? Was it caused by a specific, personal experience?

21. Who feels there should be a limit to the amount of money a jury can award in a lawsuit?

    a. Please tell us how you feel it should be limited. For example, should the jury verdict

only include the cost of medical care and other out-of-pocket expenses? Should there be a cap on the amount awarded for pain and suffering?

22. Do any of you have any ethical, religious, moral, political, philosophical or other beliefs that would prevent you from sitting in judgement of others, or applying the law to the evidence in the case?

23. Do any of you know any of the other persons on the jury panel?

Dated: June 3, 2022

Respectfully submitted,

MARTIN | BAUGHMAN, PLLC

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on the 3rd day of June, 2022, via electronic service, on counsel of record for Defendants.

/s/ Joshua V. Michaels
Joshua V. Michaels